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BMJ Open Early detection and management of major non-communicable diseases in urban primary healthcare facilities in Ethiopia: a study protocol for a type-3 hybrid implementation-effectiveness design

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ABSTRACT

Introduction Integrating early detection and management of non-communicable diseases in primary healthcare has an unprecedented role in making healthcare more accessible particularly in low- and middle-income countries such as Ethiopia. This study aims to design, implement and evaluate an evidence-based intervention guided by the HEARTS technical package and implementation guide to address barriers and facilitators of integrating early detection and management of hypertension, diabetes mellitus and cardiovascular diseases in primary healthcare settings of Addis Ababa.

Methodology We will employ a type-3 hybrid implementation-effectiveness study from November 2020 to May 2022. This study will target patients ≥40 years of age. Ten health centres will be randomly selected from each subcity of Addis Ababa. The study will have four phases: (1) Baseline situational analysis (PEN facility-capacity assessment, 150 observations of patient healthcare provider interactions and 697 patient medical record reviews), (2) Consolidated Framework for Implementation Research (CFIR) inspired qualitative assessment of barriers and facilitators (20 in-depth interviews of key stakeholders), (3) Design of intervention protocol. The intervention will have capacity enhancement components including training of non-communicable disease (NCD) service providers, provision of essential equipment/supporting materials and monthly monitoring and feedback and (4) Implementation monitoring and evaluation phase using the RE-AIM (reach, efficacy, adoption, implementation and maintenance) framework. Outcomes on early detection and management of NCDs will be assessed to examine the effectiveness of the study.

Ethics and dissemination plan Ethical clearance was obtained from the Addis Ababa University, College of Health Sciences Institutional Review Board and Addis Ababa Health Bureau. We plan to present the findings from this research in conferences and publish them in peer-reviewed journals.

Strengths and limitations of this study

- The study uses an implementation research framework to design interventions, analyse and report the findings of the study.
- The study uses a comprehensive baseline assessment of health facilities to inform the design of the intervention.
- The study will adapt the WHO HEARTS technical package and implementation guide to the local context to implement the intervention.
- The uncontrolled nature of the design might reduce the rigorousness of the study.
- As the outcome indicators for this study relies on routine medical records and observations, missing and observation bias might arise.

INTRODUCTION

Non-communicable diseases (NCDs) are the leading causes of death worldwide. Integrating cost-effective NCD interventions in primary healthcare, as the first point of care, has a great potential to reverse progression of disease, prevent complications, reduce hospitalisations, healthcare costs and out-of-pocket expenditures¹ and make healthcare accessible.² However, many African countries have health systems that do not meet the requirements for chronic disease care and are historically shaped around acute care.³ Management of NCDs is challenging especially in low- and middle-income countries due to the double burden of communicable and non-communicable diseases, lack of human and material resources and other competing economic priorities in the countries.^{4,5} The long-term nature of many NCDs demand an integrated and comprehensive

health system response⁶ and need to be sustained for a significant period of time.⁷

A total of 57 million deaths occurred globally in 2016; of which, 41 million (71%) were due to NCDs, principally cardiovascular diseases (CVD), diabetes, cancer and chronic respiratory diseases.^{8,9} NCDs are responsible for 15 million premature adult deaths (occurring in those aged 30 to 69 years). Nearly 80% of these premature deaths caused by NCDs occurred in low- and middle-income countries.¹⁰ Though communicable diseases are still the leading cause of mortality in Africa, the burden of NCDs is rising rapidly and is projected to cause almost three-quarters as many deaths as communicable, maternal, perinatal and nutritional diseases by 2020 and to exceed them as the most common causes of death by 2030.¹¹ Similarly, in Ethiopia, the burden of NCDs is increasing at an alarming rate. According to WHO country profiles, currently, NCDs are responsible for almost 39% of all deaths in Ethiopia.⁹

Strengthening the national capacity to integrate and scale-up care for major NCDs such as diabetes, CVD and respiratory disease in primary healthcare in low-resource settings were among the top recommendations.^{4,5} Over the years, the WHO has developed evidence informed guidelines to enhance the prevention, diagnosis and management of NCDs such as diabetes, CVD and respiratory disease at primary healthcare settings. Among these guidelines are the package of essential non-communicable disease (PEN) and the total risk approach where cost-effective interventions for early detection of NCDs, non-pharmacological and pharmacological approaches for modification of risk factors and affordable medications for treatment of NCDs.⁴ In addition, in 2016, the HEARTS technical package was developed as a measure to avert CVD by addressing major modifiable risk factors including tobacco use, hypertension, high blood cholesterol and diabetes.⁵ The package includes simple and affordable tools (eg, clinical measurements, simple laboratory testing, CVD risk assessment charts and blood pressure measurement devices) for early detection and treatment of CVDs. Moreover, these two guidelines are aligned and complementary to each other.⁵

Studies in sub-Saharan Africa indicated the importance of NCD integration models¹² and effectiveness of advice on diet and lifestyle modification to facilitate management of NCDs in resource poor settings.¹³ The government of Ethiopia also produced a national guideline, championing integration of early detection and management of NCDs in primary healthcare to address the national burden of NCDs.¹⁴

Despite these initiatives, there is lack of evidence on practical implementation of guidelines, as well as little research on barriers and facilitators of early detection and management of NCDs in Ethiopia.

This study aims to design, implement and evaluate an evidence-based intervention guided by the HEARTS technical package and implementation guide to address barriers and facilitators of integrating early detection

and management of hypertension, diabetes mellitus and CVDs in primary healthcare settings of Addis Ababa. The intervention will comprise capacity enhancement components including development of training module and job-aids, training of NCD service providers, provision and/or maintenance of essential equipment, guidelines and supporting materials and regular monitoring and feedback. With this study protocol, we will present how we will inform the design of the intervention and how we plan to implement and evaluate the intervention.

METHODS AND MATERIALS

Study settings

The study will be conducted in Addis Ababa, Ethiopia. Addis Ababa city administration is the capital city of the country. It is organised in 10 subcities, which are the second upper administration units next to the city administration. Addis Ababa has an estimated total population of 5.65 million, with an average density of 5645.61 people per square km. According to the 2017/2018 Health and Health Related Indicators of Ethiopia, the city has 25 hospitals and 97 health centres.¹⁵ A health centre is the health service nearest to the public, where people receive direct and primary healthcare services. In Addis Ababa, a health centre serves approximately 25 000 people under its catchment area. It provides both preventive and curative services and serves as a referral centre.¹⁶ Health centres are also the first contact points for NCD screening, detection and management. On average, health centres are staffed with 20 healthcare providers, of whom 5 healthcare providers work in adult outpatient departments (OPDs).¹⁶ Health centres report to subcity health bureaus, while the subcity health bureau is in charge of implementing a monthly mentorship programme as a standard procedure for each health centre providing NCD services in Addis Ababa. Mentors from subcities visit their respective health centres to supervise the quality of NCD services and provide written feedback to service providers and health centres.

Health centres in Addis Ababa are stratified in to 10 subcities. We excluded 27 health centres with an ongoing intervention on NCDs. From the remaining pool of 70 health centres, we randomly selected 1 health centre from each subcity to obtain a total of 10 health centres. Thus, the study will be conducted in 10 health centres (figure 1).

Study design and period

This study will employ a type-3 hybrid implementation-effectiveness design¹⁷ and will be conducted from November 2020 to May 2022. The study will be conducted in four phases, each described in detail below (figure 2):

Phase one: baseline situational analysis

This first phase will form the baseline assessment stage of the project and employ the following approaches.

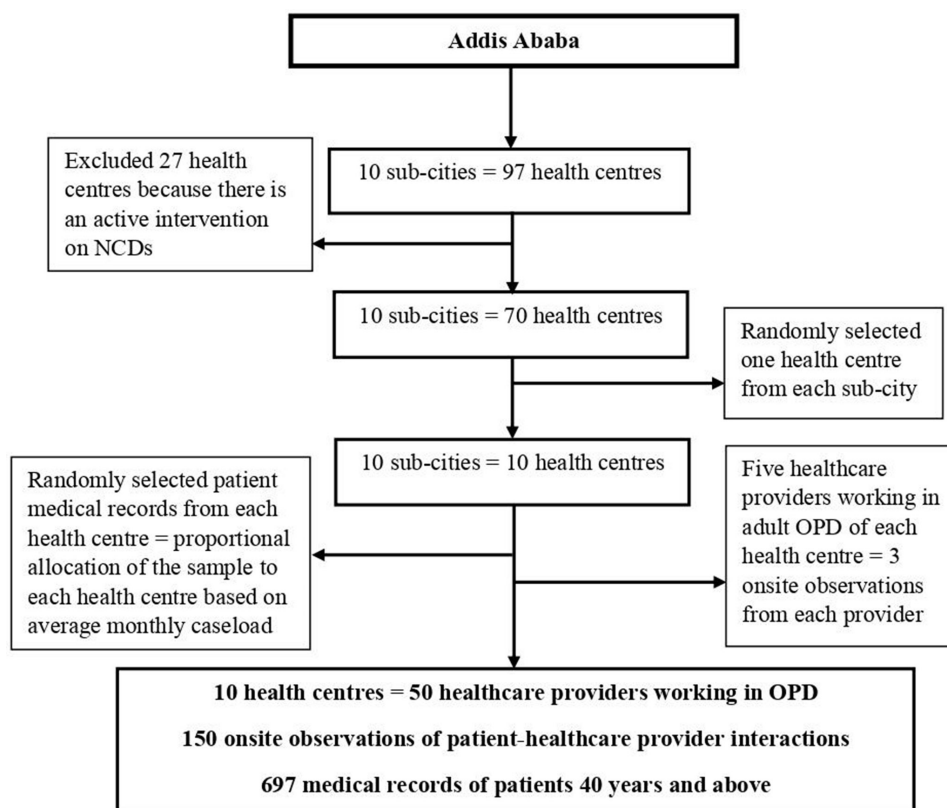


Figure 1 Sampling procedure and allocation of health centres, healthcare providers and patient medical records. NCDs, non-communicable diseases; OPD, outpatient department.

1. *Caseload of major NCDs* including hypertension and diabetes in the selected 10 health centres during the previous 3 months before the baseline data

collection will be summarised by reviewing the Health Management Information System (HMIS) reports of health centres.

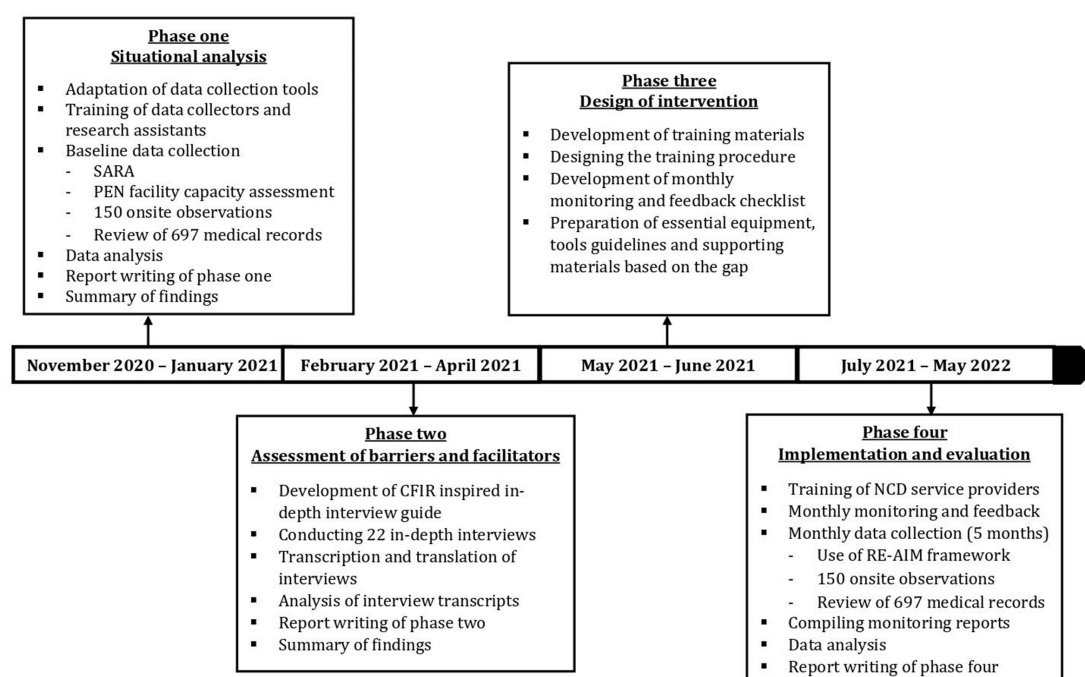


Figure 2 Schematic representation of the overall study design and timeline. CFIR, Consolidated Framework for Implementation Research; NCDs, non-communicable diseases; RE-AIM, reach, efficacy, adoption, implementation and maintenance; SARA, Service Availability and Readiness Assessment.

2. *Capacity of the selected 10 health centres* to diagnose and manage NCDs will be conducted using the PEN facility capacity assessment⁴ and Service Availability and Readiness Assessment (SARA)¹⁸ tools. The tools include assessment of availability and functionality of essential diagnostic tools, medications, laboratory facilities and tests and human resources to provide NCD services.
3. *Early detection and management of NCDs* will be assessed using the following approaches by adapting the assessment tools from WHO PEN and the clinical and programmatic management of major NCDs, Ethiopia guideline.^{14 19}
 1. *Onsite observation of patient healthcare provider interactions* of patients ≥ 40 years of age attending the OPD in the selected health centres will be conducted. The observation will be guided by an observation checklist. The checklist will include information about risk assessment, diagnosis and counselling on adherence to medication and dietary and lifestyle modifications. We will conduct three consecutive observations of patient healthcare provider interactions from each provider working in OPDs for patients ≥ 40 years of age in the selected health centres resulting in a total of 15 observations from each health centre ($n=150$) (figure 1). Data collection will be conducted on all days of the week until the desired sample size is achieved. Data will be collected at each health centre at the same time. Background information of healthcare providers including age, educational status, years of work experience and previous training on NCDs will be collected using a self-administered questionnaire after the observation.
 2. *Medical records of patients ≥ 40 years of age* during the baseline data collection will be reviewed to assess opportunistic screening, risk assessment, management of patients and extent of recording/documentation of information on assessments, medications, laboratory analysis and dietary and lifestyle characteristics of patients in the selected health centres. Patient medical records are paper based and stored in health centres. We estimated the number of patient's medical records to be reviewed using a single population proportion. The following assumption was considered to obtain the minimum sample size: the prevalence of hypertension among outpatient clients in Addis Ababa 34.7%,²⁰ 95% precision and adjusting for design effect of 2, the calculation resulted in a minimum of 697 patient medical records to be reviewed. This sample will be proportionally allocated to the selected 10 health centres based on their monthly average caseload. Sampling frame will be obtained from each health centre triage and simple random sampling will be used to select patient medical records (figure 1).

Data collection procedure of phase one

The first phase of the study will be conducted from November 2020 to January 2021. Data on baseline situational analysis will be collected by 10 health professionals. The data collection process will be overseen by five research assistants who are also health professionals. Data collectors and research assistants will be trained on the data collection process and tools by the research team.

Analysis of phase one

Data from situational analysis, PEN facility capacity assessment, SARA, observation and review of medical records will be analysed using descriptive analysis techniques and will be presented using frequency tables, percentages, mean and median.

Phase two: assessment of barriers and facilitators

In this phase two, early detection and management of major NCDs will employ a qualitative study design. The research team will develop an in-depth qualitative interview guide using a consolidated framework for implementation research, which is compatible to analyse both patient-level and system-level determinants. The framework also accounts environmental thinking by providing theory-based constructs for developing context-specific models.^{21 22} The interview guide will be prepared in English, which will then be translated to the local language Amharic by a language expert and translated back to English to verify its consistency. The in-depth interview will target key stakeholders including healthcare providers working in OPD, pharmacy, laboratory, patients ≥ 40 years of age (both patients with NCD and other conditions), health centre administrative, representatives of subcity, Addis Ababa Health Bureau, Ministry of Health, health centre HMIS and Pharmaceuticals Fund and Supply Agency (PFSA). PFSA is a sole government led supplier of medication, laboratory reagents and essential medical equipment in Ethiopia.

Data collection procedure of phase two

This phase of the study will be conducted from February 2021 to April 2021. We plan to conduct 20 in-depth interviews of key stakeholders. However, based on the saturation of the data, further theoretical sampling will be considered. Four experienced qualitative interviewers who are health professionals will conduct the in-depth interviews after receiving a training about the purpose of the study and components of the interview guide. All in-depth interviews will be audiotaped.

Consolidated Framework for Implementation Research

The aim of this study is to improve early detection and management of NCDs in primary healthcare services of Addis Ababa. It is important to understand the context of primary care facilities in order to document the nuances of the current scenario. Using theory-derived frameworks to improve the early detection and management of NCDs in low-income countries like Ethiopia will help to generate robust evidence to back up policies. Thus, we will use the

Box 1 CFIR (Consolidated Framework for Implementation Research) domains and associated constructs

1. Intervention characteristics
 - ▶ Intervention source
 - ▶ Evidence strength and quality
 - ▶ Relative advantage
 - ▶ Adaptability
 - ▶ Trialability
 - ▶ Complexity
 - ▶ Design quality
 - ▶ Cost
2. Outer setting
 - ▶ Patient needs and resources
 - ▶ Cosmopolitanism
 - ▶ Peer pressure
 - ▶ External policy and incentives
3. Inner setting
 - ▶ Structural characteristics
 - ▶ Networks and communication
 - ▶ Culture implementation climate
 - ▶ Readiness for implementation
4. Characteristics of individuals
 - ▶ Knowledge and beliefs about the intervention
 - ▶ Self-efficacy
 - ▶ Individual stage of change
 - ▶ Other personal attributes
5. Process
 - ▶ Planning
 - ▶ Engaging
 - ▶ Executing
 - ▶ Reflecting and evaluation

Consolidated Framework for Implementation Research (CFIR) framework to understand the contextual barriers and facilitators related to early detection and management of NCDs particularly hypertension and diabetes at primary healthcare level in Addis Ababa.²¹ Over the past years, the use of this framework is increasing, especially in helping healthcare systems identify why health interventions are not working and on identifying hurdles to and acceptability of new interventions. The framework is a synthesis of different implementation frameworks into one consolidated framework with 39 constructs organised under five domains (intervention characteristics, outer setting, inner setting, characteristics of individuals and process) (box 1). Our data collection tool will be designed to include all the five domains of the CFIR framework and we will try to cover as much constructs as possible depending on the saturation of the interviews.

Data analysis of phase two

Qualitative interviewers will transcribe the audiotaped in-depth interviews into Amharic and then translate it to English language. The authors of the study will verify the translated interviews against the audiotapes for accuracy. English version of the transcript will be prepared in text files and entered into Open Code software for processing and analysis. Two individuals with experience

in qualitative analysis will make the coding line by line. We will follow thematic analysis based on the domains and constructs of CFIR framework. Codes, categories, patterns and quotations will be analysed into the pre-conceived codebook from the CFIR domains and constructs as they emerge in the interview transcripts. Accordingly, the barriers and the facilitators will be identified. Along with the finding from the quantitative study, the research team will triangulate the evidence to assist further planning and development of intervention protocol.

Phase three: design of intervention protocol

During this phase, we will design an intervention protocol tailored to address barriers and adaptation of the implementation on the existing systems to improve early detection and management of patients ≥ 40 years of age. This design phase will be informed by the findings of the earlier phases and the HEARTS technical package and implementation guide.^{5 23} The intervention protocol will include the following capacity enhancement and monitoring components and will be developed from May 2021 to June 2021. The outlined intervention will be further strengthened based on the results of our baseline assessment and the identification of the barriers and facilitators.

1. *Development of training materials* including training module and job-aids guided by the findings of earlier phases and the WHO PEN and HEARTS packages. The training module will consist of information regarding early detection and management of NCDs, counselling skills, recording and reporting.
2. *Training of healthcare providers* working in OPD, laboratory pharmacy and triage, subcity mentors/supervisors, representatives from health centre administration, health centre HMIS representative, PFSA. The training will be provided by internists, endocrinologists and public health nutrition professionals from Addis Ababa University. A 3-day training will be provided once at the beginning of the implementation phase. It will include PowerPoint presentations, question and answer sessions and role-plays.
3. *Provision of guidelines and supporting materials* such as HEARTS technical package, job-aids and posters to be placed/posted inside the OPD, recording and reporting charts, copies of the national standard recording and reporting templates. Guidelines and supporting materials will be provided based on the gaps in the monthly monitoring reports throughout the implementation phase.
4. *Provision and/or maintenance of essential equipment* such as blood pressure and glucose measuring devices, weight scale, height measuring device/stadiometer and waist circumference measuring tape. Essential equipment will be provided and/or maintained based on the gaps in the monthly monitoring reports throughout the implementation phase. The study team will liaise with the Ministry of Health, Addis Ababa Health Bureau and non-governmental organisations to provide/maintain

essential equipment, guidelines and supporting materials to deliver NCD services.

5. *Facilitation of medication and laboratory reagent procurement* from the national PFSA in case of stock out throughout the implementation phase. The study team will facilitate procurement by assisting the health centres in writing procurement request before a complete stock out to allow time for the procurement process. We will also assist health centres to have regular monitoring of the availability and functionality of essential medications, reagents and equipment.
6. *Maintaining clean and comfortable environment* in NCD service rooms for patient healthcare provider consultations. The study team will make sure that NCD service rooms are clean and comfortable during the monthly monitoring.
7. *Monthly monitoring and feedback* of the NCD services will be conducted for 5 months.

Phase four: implementation, monitoring and evaluation phase

In this phase, we will implement the intervention protocol in the selected 10 health centres. After the training and provision of essential equipment, we will conduct monthly monitoring of the health centres with feedback for 5 months in addition to the regular monthly mentoring/supervision visits conducted by subcity mentors. We will adapt a checklist from WHO PEN package to guide the monitoring visits. The checklist will include availability and functionality of essential tools, medications, equipment and trained staff and regularity/functionality of the subcity mentorship and feedback programme. After each monitoring visit, a performance report will be prepared, and best practices/lessons learnt will be documented to capitalise the experience for the rest of the health centres. Appropriate written feedback will then be provided to respective health centres, NCD service providers and subcity mentors at each monitoring visit. The feedback will be provided by trained health professionals who are involved in the data collection process. We will also provide and/or maintain essential tools and equipment for health centres based on the gaps in the monitoring reports.

As part of continuous monitoring, we will assess early detection and management of NCDs every month for 5 months using the same observation checklist and patient medical records reviewing tool used during the baseline assessment. The variables in the observation checklist and patient medical record reviews will be organised using the RE-AIM framework by Glasgow *et al* (1999)²⁴ to evaluate certain dimensions of the intervention and implementation process (online supplemental table 1). The framework will assess five dimensions of the implementation at individual and organisation level; reach, efficacy, adoption, implementation and maintenance.

Outcome measures

This study will measure outcomes related to NCD detection and management at primary healthcare level.

Outcomes will be assessed through review of patient medical records, onsite observation of patient healthcare provider interactions, review of HMIS reports and monthly monitoring reports.

The outcomes to be measured in this study are as follows: Further, key outcome measures of the study under each dimensions of the RE-AIM framework are presented as a supplement along this paper (online supplemental table 1). We will display outcome measures for each data collection month from baseline to end line.

1. **Assessment and counselling:** % of individuals ≥ 40 years of age for whom blood pressure, blood glucose and waist circumference measured, % of individuals ≥ 40 years of age for whom cardiovascular risk estimated and % of individuals ≥ 40 years of age who received dietary and lifestyle counselling in each month of data collection.
2. **Treatment and control of NCDs:** effectiveness of NCD management and control programme will be evaluated using indicators such as % of individual who received antihypertensive and antidiabetic medications, % of individuals with blood pressure $>140/90$ mm Hg, % individuals with random blood sugar >140 mg/dL or fasting blood sugar >110 mg/dL, % individuals with cardiovascular risk $>30\%$, % of individuals with high waist circumference (>80 cm in women and >90 cm in men), % individuals with hypertension and diabetes related complications and % individuals with lifestyle modifications in each month of data collection.

Data collection procedure of phase four

Phase four of the study will be conducted from July 2021 to May 2022. Trained health professionals involved during the baseline data collection and monitoring will collect data for this phase.

Analysis of phase four

Monthly monitoring reports will be compiled to produce a summary of the reports including best practices/lessons learnt and feedbacks. Data from observation checklists and review of medical records will be analysed using descriptive analysis techniques such as frequencies, percentages, mean and median. Monthly data for all collected variables will be presented in a table to show the changes/progresses each month. Trend of monthly reports will be compared using X^2 for trend analysis.

DISCUSSION

A comprehensive understanding of the organisational situations, readiness, service availability and barriers and facilitators to early detection and management of NCDs are important to implement an innovative approach to integrate the service at the primary healthcare level. In addition, locally customised intervention towards NCDs

will enhance the overall healthcare system and help policymakers to make evidence informed decisions.

In this study, a representative sample, one health centre from each subcity in Addis Ababa was selected. We excluded health centres with an ongoing intervention. Furthermore, the study aims to derive learning from context and develop a set of working interventions and best practices, which can be transferred to other settings. Thus, the findings from this study can be generalised to urban settings of Ethiopia and could serve as a lesson for other places with similar setting.

ETHICS AND DISSEMINATION

Ethical considerations

Ethical clearances were obtained from the Institutional Review Board (IRB) of the College of Health Sciences of the Addis Ababa University and Addis Ababa Health Bureau ethical review committee, with ethical clearance reference number 070/18/IM, dated 24 December 2018. Informed consent to participate in the study will be obtained from individual participants and selected health centres. All respondents will be provided the name, telephone number and email of the principal investigator and IRB contact details to contact if they have any questions about the study.

Dissemination plan

The main target audience for this study include Ministry of Health officials, policymakers, programme implementers, health workers, researchers and non-governmental organisations working to improve emerging health problems in low- and middle-income countries. Moreover, the finding from this study will help improve early detection of NCDs for populations at grass root level attending primary healthcare facilities. Any interested group can use this evidence to help improve early detection and management of NCDs health services.

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

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Contributors HY, SG, ND, AF and THG conceived the project. HY, AO and AK designed development of situational analysis, intervention and implementation, monitoring and evaluation plan. All authors contributed to the refinement of situational analysis, intervention and implementation, monitoring and evaluation

plan. HY, AO and AK wrote the first draft of the manuscript. SG, ND, AF, THG and AM revised the manuscript draft. All authors contributed to the refinement of the study protocol and approved the final manuscript.

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